

REMARKS

Initially, Applicants would like to express appreciation to the Examiner for the detailed Final Official Action provided.

Claims 1, 3-7, and 10-17 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 1, 3-7, and 10-17 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

Claims 1, 4-7, and 10-13 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over REDDING (U.S. 2002/0156415) in view of TALISH et al. (U.S. 7,211,060) and HIDAKA et al. (U.S. Patent No. 4,990,340).

However, Applicants note that REDDING, TALISH et al., and HIDAKA et al. fail to teach or suggest the subject matter claimed in claims 1 and 7. Independent claim 1 sets forth an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles including, inter alia, an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit that controls irradiation conditions of the irradiation unit; “wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles”. Independent claim 7 sets forth “an ultrasonic percutaneous penetration kit, which, upon allowing a medicine containing an active ingredient to penetrate an organism from a skin surface, allows vibration of ultrasonic waves to penetrate the organism from the skin surface to whiten skin or reduce skin wrinkles” including, inter alia, a medicine containing an active ingredient; an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit; “wherein the control unit

controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles”.

The Examiner has taken the position that it would have been obvious to provide the REDDING device with a frequency between 3-7 MHz as taught by TALISH et al., and with the particular active ingredient as taught by HIDAKA et al.

However, Applicants note that a presumption of obviousness based on a claimed invention that falls within a prior art range may be rebutted by showing “(1)]hat the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art”. See particularly the Manual of Patent Examining Procedure § 2144.05 III.

In Applicants’ claimed invention, ultrasonic waves are used to provide effective penetration of a medicine into the patient’s tissue.

The REDDING patent discloses an ultrasonically enhanced substance delivery device. In the REDDING device, a substance such as a pharmaceutical compound is penetrated through a patient’s skin via the ultrasonically enhanced substance delivery. As recognized by the Examiner, REDDING fails to teach or suggest controlling the frequency of the ultrasonic waves within a range from 3 to 7 MHz.

The TALISH et al. patent discloses an ultrasound bandage that heals wounds by applying acoustic energy to the wound. As described in the TALISH et al. patent, the ultrasound bandage heals a wound by application of the acoustic energy to the wound. The TALISH et al. device does not use the ultrasonic waves to deliver an ingredient to the patient to heal the wound. In other words, it is the acoustic energy, itself, that heals the wounds. TALISH et al. does not deliver any substance to the wound. TALISH et al. discloses that a sonically conductive

material, such as a gel, may be used to improve the coupling between the ultrasonic bandage and the patient's skin, but TALISH et al. does not disclose or teach that the sonically conductive material or a constituent of the sonically conductive material is delivered to the patient by the acoustic energy. See column 6, lines 34-42. Thus, TALISH et al. does not disclose or teach a method in which ultrasonic energy is used to penetrate a patient's skin and deliver an ingredient to a patient. Accordingly, it is respectfully submitted that the TALISH et al. patent teaches away from providing an ultrasonic wave frequency from 3 to 7 MHz, and that, therefore, the Examiner's rejection on obviousness has been rebutted by showing that the prior art taught away from the claimed invention. MPEP § 2144.05 III.

Therefore, since the TALISH et al. patent teaches away from providing an ultrasonic wave frequency from 3 to 7 MHz in the REDDING device and method, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 1 and 7 under 35 U.S.C. § 103(a) over REDDING in view of TALISH et al. and HIDAKA et al. Thus, the only reason to combine the teachings of REDDING, TALISH et al., and HIDAKA et al. results from a review of Applicants' disclosure and the application of impermissible hindsight.

Further, HIDAKA et al. fails to teach or suggest a device or method for providing ultrasonic waves for penetrating a preparation to a patient's skin. Accordingly, HIDAKA et al. fails to teach or suggest a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles.

Therefore, the TALISH et al. and HIDAKA et al. patents fails to cure the deficiencies of the REDDING device, and even assuming, arguendo, that the teachings of REDDING, TALISH et al., and HIDAKA et al. have been properly combined, Applicants' claimed ultrasonic

percutaneous penetration device to whiten skin or reduce skin wrinkles including a control unit that controls the frequency of ultrasonic waves to whiten skin or reduce skin wrinkles as set forth in claims 1 and 7 would not have resulted from the combined teachings thereof.

Accordingly, the rejection of claims 1, 4-7, and 10-13 under 35 U.S.C. § 103(a) over REDDING in view of TALISH et al. and HIDAKA et al. is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claims 3-6 and 10-13, which are at least patentable due to their dependency from claims 1 and 7 for the reasons noted above, recite additional features of the invention and are also separately patentable over the prior art of record based on the additionally recited features.

Claims 14-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over REDDING (U.S. 2002/0156415) in view of MCDANIEL et al. (U.S. 6,030,374).

However, Applicants note that REDDING and MCDANIEL fail to teach or suggest the subject matter claimed in claims 14-17.

Independent claim 14 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "simultaneously as a medicine containing an active ingredient is made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through the medicine to whiten skin or reduce skin wrinkles". Independent claim 15 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "after a medicine containing an active ingredient has been made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through a medium that transmits ultrasonic waves to whiten skin or reduce skin

wrinkles". Independent claim 16 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "after having applied ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface to whiten skin or reduce skin wrinkles, a medicine containing an active ingredient is made in contact with the skin to which the ultrasonic waves have penetrated". Independent claim 17 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "selecting two or more processes from the following three processes: a process in which a medicine containing an active ingredient is made in contact with the skin; a process in which ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface to whiten skin or reduce skin wrinkles; and a process in which, simultaneously as the medicine containing an active ingredient is made in contact with the skin, ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface through the medicine to whiten skin or reduce skin wrinkles".

The Examiner has taken the position that it would have been obvious to use the device of REDDING for lightening the skin, to function at a frequency between 3 and 7 MHz, and to apply vitamin C or kojic acid as taught by MCDANIEL.

However, Applicants note that a presumption of obviousness based on a claimed invention that falls within a prior art range may be rebutted by showing "(1) that the prior art taught away from the claimed invention...or (2) that there are new and unexpected results relative to the prior art". See particularly the Manual of Patent Examining Procedure § 2144.05 III.

In the instant invention, ultrasonic waves provide effective penetration of a medicine into the patient's tissue.

The REDDING patent discloses an ultrasonically enhanced substance delivery device and method in which a substance, such as a pharmaceutical compound, penetrates through a patient's skin via the ultrasonically enhanced substance delivery. As recognized by the Examiner, REDDING fails to teach or suggest the method of lightening the skin, controlling the frequency of the ultrasonic waves within a range from 3 to 7 MHz, and providing the particular active ingredients.

The MCDANIEL patent teaches ultrasound enhancement of percutaneous drug absorption. As described in the MCDANIEL patent, the ultrasound enhancement method includes lightening uneven or extra pigment or reducing wrinkles, applying ultrasonic frequency in a range, and applying vitamin C as an active ingredient. MCDANIEL teaches a range of ultrasonic frequency of between 25 KHz and 3 MHz for a lower frequency range; and a range of ultrasonic frequency of between 3 MHz and 16 MHz for a higher frequency range. However, MCDANIEL does teach any particular range of the disclosed ranges that should be applied for lightening pigment or for reducing wrinkles. See column 7, lines 34-54. Moreover, the MCDANIEL patent specifically teaches lightening uneven or extra pigment, but does not teach or suggest whitening skin. Since lightening uneven or extra pigment (as taught by MCDANIEL) is not the same as whitening the skin, the MCDANIEL patent does not teach or suggest whitening the skin. Thus, MCDANIEL does not teach or suggest a method of whitening skin or reducing wrinkles and controlling the frequency of the ultrasonic waves to a frequency within a range from 3 MHz to 7 MHz to whiten skin or reduce wrinkles. Accordingly, it is respectfully submitted that the MCDANIEL patent teaches away from whitening skin or reducing wrinkles and controlling the frequency of the ultrasonic waves to a frequency within a range from 3 MHz to 7 MHz to whiten skin or reduce wrinkles, and that, therefore, the Examiner's rejection based

on obviousness has been rebutted by showing that the prior art taught away from the claimed invention. MPEP § 2144.05 III.

Therefore, since the MCDANIEL patent teaches away from whitening skin or reducing wrinkles and controlling the frequency of the ultrasonic waves to a frequency within a range from 3 MHz to 7 MHz to whiten skin or reduce wrinkles in the REDDING device and method, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 14-17 under 35 U.S.C. § 103(a) over REDDING in view of MCDANIEL. Thus, the only reason to combine the teachings of REDDING and MCDANIEL results from a review of Applicants' disclosure and the application of impermissible hindsight.

Therefore, the MCDANIEL patent fails to cure the deficiencies of the REDDING device, and even assuming, arguendo, that the teachings of REDDING and MCDANIEL have been properly combined, Applicants' claimed use of an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles including a control unit that controls the frequency of ultrasonic waves to whiten skin or reduce skin wrinkles as set forth in claims 14-17 would not have resulted from the combined teachings thereof.

Accordingly, the rejection of claims 14-17 under 35 U.S.C. § 103(a) over REDDING in view of MCDANIEL is improper for all the above reasons and withdrawal thereof is respectfully requested.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection, and an early indication of the allowance of claims 1, 3-7, and 10-17.

SUMMARY AND CONCLUSION

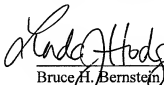
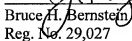
In view of the foregoing, it is submitted that the present response is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 1, 3-7, and 10-17. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, consideration of the present response, reconsideration of the outstanding Official Action, and allowance of all of the claims in the present application are respectfully requested and now believed to be appropriate.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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